§ 862.1820 Xylose test system.

(a) *Identification.* A xylose test system is a device intended to measure xylose (a sugar) in serum, plasma, and urine. Measurements obtained by this device are used in the diagnosis and treatment of gastrointestinal malabsorption syndrome (a group of disorders in which there is subnormal absorption of dietary constituents and thus excessive loss from the body of the nonabsorbed substances).

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

[52 FR 16122, May 1, 1987, as amended at 65 FR 2308, Jan. 14, 2000]

§ 862.1825 Vitamin D test system.

(a) *Identification.* A vitamin D test system is a device intended for use in clinical laboratories for the quantitative determination of 25-hydroxyvitamin D (25–OH–D) and other hydroxylated metabolites of vitamin D in serum or plasma to be used in the assessment of vitamin D sufficiency.

(b) *Classification.* Class II (special controls). Vitamin D test systems must comply with the following special controls:

(1) Labeling in conformance with 21 CFR 809.10 and

(2) Compliance with existing standards of the National Committee on Clinical Laboratory Standards.

[63 FR 40366, July 29, 1998]

Subpart C—Clinical Laboratory Instruments

§ 862.2050 General purpose laboratory equipment labeled or promoted for a specific medical use.

(a) *Identification.* General purpose laboratory equipment labeled or promoted for a specific medical use is a device that is intended to prepare or examine specimens from the human body and that is labeled or promoted for a specific medical use.

(b) *Classification.* Class I. The device identified in paragraph (a) of this section is exempt from the premarket notification procedures in subpart E of part 807 and is exempt from the current good manufacturing practice regulations in part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 862.2100 Calculator/data processing module for clinical use.

(a) *Identification.* A calculator/data processing module for clinical use is an electronic device intended to store, retrieve, and process laboratory data.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807.

[52 FR 16122, May 1, 1987, as amended at 53 FR 21449, June 8, 1988]

§ 862.2140 Centrifugal chemistry analyzer for clinical use.

(a) *Identification.* A centrifugal chemistry analyzer for clinical use is an automatic device intended to centrifugally mix a sample and a reagent and spectrophotometrically measure concentrations of the sample constituents. This device is intended for use in conjunction with certain materials to measure a variety of analytes.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9.

[52 FR 16122, May 1, 1987, as amended at 65 FR 2308, Jan. 14, 2000]

§ 862.2150 Continuous flow sequential multiple chemistry analyzer for clinical use.

(a) *Identification.* A continuous flow sequential multiple chemistry analyzer for clinical use is a modular analytical instrument intended to simultaneously perform multiple chemical procedures using the principles of automated continuous flow systems. This device is intended for use in conjunction with certain materials to measure a variety of analytes.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures